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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,649	05/25/2006	Svend Erik Borgesen	BORGESEN=4A	5773

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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,649	BORGESEN, SVEND ERIK	
	Examiner	Art Unit	
	LESLIE R. DEAK	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 34-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 34-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 May 2006* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. Claims 1-10, 34-47, are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0045847 to Borgesen in view of US 6,585,677 to Cowan et al, further in view of US 6,383,159 to Saul et al.

With regard to claims 1-10, 42, Borgesen discloses a method for shunting excess cerebrospinal from a brain ventricle to a patient's sinus system, which may comprise the transverse sinus (see paragraphs 0002, 0003, 0058). The method comprises the steps of providing a shunt system where in the shunt system comprises

- a shunt body 10 allowing fluid communication between a ventricle 21 and ventricular sinus, wherein the shunt body comprises a flow restricting component 16 (see FIG 8, paragraph 0052),
- brain ventricle catheter 15 capable of being connected to the shunt body and draining CSF from the ventricle to the shunt body (see at least paragraph 0053)
- a sinus catheter 18 (se at least paragraph 0055) connected to the shunt body, wherein the sinus catheter is capable of draining to the sinus system the fluids from the ventricle, and passed through the flow restrictor

The apparatus, including shunt body, ventricular, and sinus catheter, are disclosed as being made of a biocompatible material and may operate at less than 7Hg/mL/min (see, generally, paragraphs 0031, 0052). Borgesen further discloses the steps of inserting the ventricular catheter into the patient, inserting the sinus catheter into the patient,

connecting the catheters to the shunt body, and removing toxic substances, such as excess CSF, from the ventricle to the sinus (see page 6, claim 26).

With regard to Applicant's recitation of a particular coating on the shunt body, Cowan discloses a CSF shunt that may comprise an adhesion-resistant coating, which corresponds to Applicant's "inert surface preventing biological material from maintaining contact with the inert surface." It would have been obvious to one having ordinary skill in the art at the time the invention was made to coat the shunt disclosed by Borgesen with an adhesion resistant material as disclosed by Cowan, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP § 2144.07.

Borgesen does not disclose the specific step of treating a patient with a toxic substance within the CSF, nor the step of shunting particular toxins to the sinus system. The Borgesen method comprises the steps of providing a shunt system with a flow restrictor, brain ventricle catheter, and sinus catheter, inserting the shunt system, and shunting CSF from the brain ventricle to the sinus system. However, Saul discloses a device and method for treating patients wherein the CSF of a selected patient may comprise a toxin that results in lesions of the brain. Saul discloses that the conditions that may be treated by the disclosed method comprise Alzheimer's disease, Down's Syndrome, hereditary cerebral hemorrhage with amyloidosis of the Dutch-Type, epilepsy, Parkinson's disease, polyneuropathies, and Guillain-Barre Syndrome (see column 3, lines 28-46). Therefore, it would have been obvious to one having ordinary

skill in the art at the time of invention to use the method disclosed by Borgesen to treat patients at risk of the conditions listed by Saul, since Saul discloses that such conditions may be treated by shunting excess toxins from a patient's brain.

With regard to claim 9, Saul discloses that the toxic substance removed by shunting may comprise tau or alpha-beta 42 (see column 1, lines 37-42) in order to forestall the onset or progression of various ailments. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to use the method disclosed by Borgesen to remove the toxins disclosed by Saul, since Saul discloses that such toxins may be removed in order to forestall the onset or progression of various ailments.

With regard to claim 34, Borgesen discloses that the flow restricting passage comprises a tubular structure (see paragraph 0026).

With regard to claims 35-38, Borgesen discloses that the internal radius of the flow-restricting passage may be less than 0.20mm and the length 22.1mm (which may be divided into two parts), which is within the range claimed by applicant (see paragraphs 0033, 0035, 0036).

With regard to claim 39, Borgesen further discloses the steps of inserting the ventricular catheter into the patient, inserting the sinus catheter into the patient, connecting the catheters to the shunt body, and removing toxic substances, such as excess CSF, from the ventricle to the sinus (see, generally, claim 26).

With regard to claims 40 and 41, Borgesen discloses a method for shunting excess cerebrospinal fluid from a brain ventricle to a patient's sinus system, particularly, the saggital sinus (see at least paragraph 0052).

With regard to claims 43-47, Borgesen discloses that the apparatus may comprise a ball check valve wherein the check valve provides no fluid resistance to the CSF, rendering fluid flow resistance independent of the check valve with the check valve operating independently of the fluid pressure threshold (see paragraph 0040).

Response to Arguments

2. Applicant's arguments, filed 9 July 2009, with respect to the rejection(s) of the pending claim(s) over the combination of Borgesen and Cowan have been fully considered and are persuasive.

3. However, upon further consideration, a new ground(s) of rejection is made in view of Borgeson, Cowan, and Saul, as presented above.

4. Applicant argues that the combination of Borgeson and Cowan fail to disclose the step of selecting and treating a specific subset of patients. The Examiner agrees, and has added the Saul reference to address the amended limitations.

5. Applicant argues that Saul cannot be combined with the teachings of Borgesen and Cowan because Saul is drawn to a shunt with a variable resistance valve, while Borgesen and Cowan teach the use of single-resistance valves. Applicant asserts that converting Cowan and Borgesen to a variable resistance system, as "demanded" by Saul, would prevent the prior art shunts from being used in the instantly claimed

method. However, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, the Examiner is relying on Saul merely to teach that the method of using cerebrospinal shunts to treat various conditions by shunting particular compounds to another location is known in the art. Using a known device (such as that disclosed by the combination of Borgesen and Cowan) to perform a known procedure (such as that disclosed by Saul) is, on its face, an obvious combination of the elements of the prior art. Applicant gives no objective evidence as to why the Saul procedure cannot be performed with the Borgesen-Cowan apparatus, but rather asserts only that the Saul apparatus cannot be used in the instantly claimed method. The Examiner is not proposing the use of the Saul shunt, but rather relies upon Saul to teach the step of treating particular conditions.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
15 October 2009